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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,272	11/26/2003	Golden S. Hinton	21112.006USA	8641
7590	03/10/2006		EXAMINER	
E.J. Asbury III E.J. Asbury III 3330 Cumberland Blvd. Suite 500 Atlanta, GA 30339-5985			PRIEBE, SCOTT DAVID	
			ART UNIT	PAPER NUMBER
			1633	
DATE MAILED: 03/10/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/723,272	<b>Applicant(s)</b> HINTON, GOLDEN S.	
	<b>Examiner</b> Scott D. Priebe, Ph.D.	<b>Art Unit</b> 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Objections***

Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 22 is limited to the action of antibiotics to “spill” the DNA/RNA into the bloodstream. Claim 25 allows the rupture of the bacteria to be induced by means other than by action of the infused antibiotics, which are outside the scope of claim 22, i.e. “the immune system, or any other mechanism of rupture of a cell”.

#### ***Claim Rejections - 35 USC § 101***

Claims 22-26 are rejected under 35 U.S.C. 101 for the reasons of record set forth in the Office action of 7/21/05 applied to claims 1-21, because the disclosed invention is inoperative and therefore lacks utility.

Applicant's arguments filed 7/21/05 have been fully considered but they are not persuasive. Applicant asserts that the claims as rewritten are directed to an invention that is operable, and points to the case study presented in the specification in support for Applicant's theory that the claimed invention is operative. In response, the new claims require that the effect of producing septicemia by administration of live bacteria followed by antibiotic treatment in

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order to effect lysis (rupture) of the bacterial cells is that the bacterial DNA and RNA will be utilized by the patient's repair enzymes to repair broken, damaged or distorted DNA of a cancerous cell in order to "cure" the cancer. Applicant has not addressed or rebutted the scientific evidence provided in the earlier rejection showing that the bacterial DNA and RNA cannot be used by the patient's repair enzymes to repair mutations that gave rise to the cancer cell, and thus cannot "cure" the cancer. With respect to the case study presented in the specification, the specification presents no evidence to show that the reported infection suffered by the patient had any causative role in the spontaneous remission of her cancer, as opposed to being coincidental, much less that repair of damaged DNA in cancer cells using bacterial DNA or RNA occurred or had anything to do with the remission of the cancer.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has not indicated where or how the original disclosure supports the newly presented claims, as is Applicant's burden. See MPEP 714.02, last sentence of the third

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paragraph from the end and 2163.06 (I) last sentence. Applicant has introduced new matter into the claims for the reasons set forth below.

Claim 22 recites “the quantitative intravenous infusion of ... bacteria.” While the original specification describes delivery of the bacteria by intravenous infusion, no mention is made of such infusion being “quantitative,” or any other narrower type of intravenous infusion. This grounds of rejection also applies to dependent claims 23-25, and would be overcome by deletion of “quantitative.”

Claim 24 is directed to the infusion of different species of bacteria either together or separately and “that may act synergistically to effect a cure.” The original specification does not mention or otherwise disclose delivering different species of bacteria in the context of the claimed method, much less separately or together or a synergistic combination of bacteria.

The specification is silent on these new limitations of the originally described invention. Thus, there is no evidence that Applicant had contemplated or was in possession of these newly claimed variations on the originally described invention.

Claims 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 24 recite “effects a cure” and claim 23 recites “the cure.” The specification does not define what it meant by “cure” in the context of the claimed invention, and it is unclear what the metes and bounds of the term are. It is unclear if the claims require that all cancer cells

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therapeutic effect, such as remission for a few years or temporary shrinkage of a tumor, would also constitute a “cure”.

### ***Double Patenting***

Applicant is advised that should claim 22 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 23 recited that “components of the bacterial cell other than DNA and RNA, may contribute to the cure of cancer by means as yet unknown.” This limitation does not require that the other components make such a contribution. The claim permits that they may not. There are only two possible outcomes, either the “other components” do or do not “contribute.” Claim 23 embraces both outcomes, and so does claim 22. Thus, claims 22 and 23 are identical in scope.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

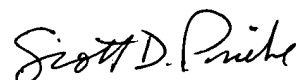
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Scott D. Priebe, Ph.D.  
Primary Examiner  
Art Unit 1633